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(54) **Pain blocking bandage.**

(57) A bandage (20) to be applied adjacent to an injured portion of a person's body contains electronic circuitry which delivers electrical pulses into the body to block or mask the pain arising from the injury. The bandage (20), when assembled and so applied, includes an inner unit (22) adapted to be applied directly onto the patient's skin (S). The inner unit (22) includes spaced-apart chambers (32)(34), each of which contains an electrolyte (52), which contacts the skin (S). Electrodes (42)(44) formed of dissimilar metals, and thereby having different electrochemical activity, are in contact with the electrolyte (52), to create a constant voltage to be delivered into the person's body. The outer unit (24) includes power cell means (70), which create a separate voltage, and an electronic circuit (68), which coverts that voltage into pulses or spikes. The inner and outer units fit together in use, and are electrically coupled by an electrical circuit coupling arrangement which, superimposed the voltage spikes from the outer unit (24) upon the constant voltage from the inner unit (22). The resultant pulsing voltage is delivered to the person's skin (S), to form current pulses in the person's body, which serve the pain blocking function.

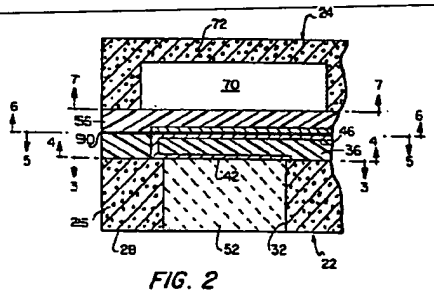


FIG. 2

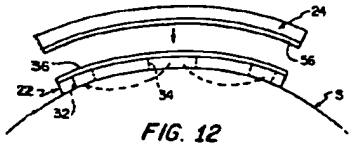


FIG. 12

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Title: PAIN BLOCKING BANDAGE

This invention relates to a pain-blocking bandage which can be applied adjacent to the injured portion of a patient's body and which blocks or masks the pain arising from the injury. More specifically, this invention relates to a novel, flexible, self-contained bandage which utilizes electrical energy to create pulsing pain-blocking low electrical currents in the patient's body.

The concept of utilizing electrical energy applied to the human body for therapeutic purposes is extremely old and well known. History records that as early as 46 A.D., the Romans used electrical torpedo fish for the treatment of arthritis, headache and gout. Throughout the centuries following, various medical researchers have used electrical energy and electrical stimulation of the body for therapeutic, curative and other purposes.

In more recent times, experimentation with the application of electrical energy to the human body has led to the discovery of an unexpected and beneficial attribute, namely, the treatment of pain. Without discussing this attribute in great detail, since detailed discussions are set forth in available medical literature, it can be generally stated that the treatment of pain by electrical stimulation falls into an area known as transcutaneous electrical neuro-stimulation, also known as TNS or TENS. With the use of these techniques, it has been found that the electrical currents somehow block or mask the transmission of pain signals by the peripheral nervous system and through the central nervous system to the brain. As a result, even though the condition which causes the pain might still remain, the patient is greatly relieved because the sensation of pain is alleviated.

Many of the advances in the field of electrical stimulation of the human body have arisen since the year 1965 when Melzack and Wall published an article entitled "Pain Mechanisms: A New Theory" relating to the "gate" theory of pain. A subsequent article by Wall and Sweet entitled "Temporary Abolition of Pain in Man" demonstrated that stimulation of the primary afferent neuron led to pain relief. While certain aspects of the "gate" theory are now considered questionable, the mere publication of these articles encouraged a renewal of interest in the whole field of electrical stimulation and led to awakened research by many different individuals, companies, hospitals and research institutions. As an outgrowth of this awakened research, new types of apparatus have been devised, developed and marketed for the purpose of delivering electrical stimulation to portions of the human body.

The apparatus which has been developed to take advantage of the discoveries relating to electrical stimulation of the body has essentially been of two general types. One type is the rather large, expensive, stationary machines which are installed in a building, such as a research institution or a doctor's office, where the patient must visit the location of the machine and be connected to the machine to receive treatment. The other type is the portable unit, usually of the TENS type, which includes a small body-carried, battery operated unit having a pair of electrodes connected by leads to the unit. The unit itself is carried by the patient as, for instance, by attachment to the patient's belt, and the electrodes are then applied to different portions of the user's body. An example of this type of unit is disclosed in U.S. Patent No. 4,014,347, issued March 29, 1977.

While these known forms of apparatus have indeed represented medical advances, there are nevertheless certain drawbacks and deficiencies associated with them. Certainly, in connection with the large stationary machines, the utility of such a machine for any particular patient is limited to the time when the patient can visit and be connected with that machine. Thus, such a machine is incapable of providing continuous treatment of an ambulatory patient. With respect to the smaller portable TENS units, these units do offer the advantage of treatment of an ambulatory patient, but they likewise are not entirely satisfactory. That is, such units are quite expensive, often costing several hundred dollars, and while a patient with severe or chronic pain might consider such a cost to be worthwhile, the average patient with a minor or temporary pain such as a sprained ankle or muscle pull is unlikely to be willing to make such an investment. Additionally, existing forms of TENS units require placement of and removal of the electrodes, often using electrode gel, at precise locations on the patient's body. The patient must be trained as to where and how to apply the electrodes, how to remove the same, how to recharge the batteries, and other mechanical aspects of the system. Also, the use of wires extending from the unit to the electrodes presents an unsightly appearance, and such patients must therefore use the device in private or suffer the embarrassment of being seen in public with wires projecting from the electrodes to the power unit. Also, the patient is able to adjust or alter the stimulation pattern or strength prescribed by the physician, with the possibility that such adjustment could render the device ineffective. Still further, existing froms of TENS units can treat only limited areas of the body since there are only two or four electrodes provided on the unit.

With the foregoing in mind, it is an object of the present invention to overcome the difficulties, deficiencies and shortcomings associated with existing forms of electrical stimulation units, and to provide instead, a new and improved unit in the form of a bandage which is capable of creating pain blocking signals which are transmitted into a person's body to block the pain arising from an injury.

Another object of the present invention is to provide a pain-blocking bandage which is self-contained in that it need not be connected with any external power supply to render it operative.

Another object of the present invention is to provide a pain-blocking bandage which is flexible enough to permit it to conform to an injured portion on a person's body.

Another object of the present invention is to provide a pain-blocking bandage which is light-weight and which can be applied to and carried by a portion of a person's body without undue discomfort.

Another object of the present invention is to provide a pain-blocking bandage which is relatively flat and which has no projecting wires or other protruberances to be attached to an external source, thereby enabling the bandage to be worn without presenting any unsightly or embarrassing appearance.

Another object of the present invention is to provide a pain-blocking bandage which is relatively inexpensive so that it can be applied to a patient's body, used continuously until the electrical energy has been dissipated, and then discarded.

Another object of the present invention is to provide a pain-blocking bandage which can be worn continuously by a patient and which need not be removed for recharging purposes.

Another object of the present invention is to provide a pain-blocking bandage which becomes operative upon application to the patient's body, and which thus needs no special training or skills on the part of the patient in order to receive the beneficial effects of the bandage.

Another object of the present invention is to provide a pain-blocking bandage which includes a pair of separable units to enable one of such units to be easily replaced when it becomes inoperative while the other unit still remains operative.

Another object of the present invention is to provide a pain-blocking bandage which becomes operative upon application to a patient's body and which remains in continuous operation for the effective life of the bandage.

Another object of the present invention is to provide a pain-blocking bandage which is formed by a pair of separate units, each of which contains a voltage generating circuit, such circuits being coupled when the units are combined to form a bandage.

Other objects, advantages and salient features of the present invention will become apparent from the following detailed description, which, taken in conjunction with the annexed drawings, discloses preferred embodiments thereof.

The foregoing objects are attained by providing a bandage which is formed of two separate units which are interconnected one on top of the other in actual usage. The first or lower unit which is applied directly onto the patient's body includes a housing or body having a pair of spaced apart openings therein, each of which is filled with an electrolyte. The underside of the housing is applied directly against the patient's skin and the upper side of the housing carries a pair of electrodes, one of which contacts the electrolyte in each of the separate openings. Advantageously, the electrodes are carried on the underside of a printed circuit board which is attached to the upper surface of the housing. This printed circuit board can be denominated a first printed circuit board. The electrodes are interconnected and are formed of dissimilar metals, and, as a result, when they contact the electrolyte, and the electrolyte, in turn, contacts the patient's skin, a circuit is formed. Because of the different electrochemical activity of the electrodes, an ionic reaction occurs in the electrolyte which causes a substantially constant voltage to be generated and transmitted through the electrolyte to the patient's body.

The second or upper unit of the present invention is mounted upon the first unit. Advantageously, a second printed circuit board forms the underside of the second unit, with the underside of the second printed circuit board being disposed directly above the upper side of the first printed circuit board. The second or upper unit includes at least one power cell which generates a D.C.

voltage and an electronic circuit which converts this voltage into a series of discrete voltage spikes or pulses. Advantageously, this electronic circuit is provided at least in part on the upper surface of the second printed circuit board.

The upper side of the first printed circuit board and the underside of the second printed circuit board form confronting surfaces which are provided with electrical coupling means, advantageouly inductive coupling means. This coupling means is provided by a first inductive coil on the upper side of the first printed circuit board and a second inductive coil on the underside of the second printed circuit board. These inductive coils effectively provide a transformer which functions to superimpose the voltage spikes from the upper unit onto the constant voltage created by the lower unit, thereby creating a resultant pulsing voltage which is delivered through the electrolyte and to the patient's skin. Because of the skin resistance of the patient's body, this resultant pulsing voltage creates a pulsing low current in the patient's body, accompanied by a magnetic field force, the effect of which is to block or mask the pain sensations arising from the injury to which the bandage is applied.

The upper and lower members are both relatively thin and are both formed advantageously of foam plastics or other suitable flexible and partially compressible material. The printed circuit boards are advantageously printed on a very thin plastics film such as Mylar. As an alternative embodiment, still within the scope of the invention, both the first and second printed circuit boards can be attached to only one of the units rather than being attached to separate units. As a result, the entire bandage unit is not only self-contained, in that it carries all of the electrical components needed to create the pain-blocking signals, but in addition is relatively flexible to enable the bandage to conform to that portion of the patient's body which is injured.

Referring now to the drawings, which form a part of this original disclosure:

Fig. 1 is a perspective view of a pain-blocking bandage in accordance with the principles of the present invention;

Fig. 2 is a greatly enlarged fragmentary sectional view taken along the line 2-2 of Fig. 1;

Fig. 3 is a top plan view of the lower housing or body unit, looking in the direction of the line 3-3 of Fig. 2;

Fig. 4 is a bottom plan view of the first printed circuit board, looking in the direction of the line 4-4 of Fig. 2;

Fig. 5 is a top plan view of the first printed circuit board, looking in the direction of the line 5-5 of Fig. 2;

Fig. 6 is a bottom plan view of the second printed circuit board, looking in the direction of the line 6-6 of Fig. 2;

Fig. 7 is a bottom plan view of the upper unit, looking in the direction of the line 7-7 of Fig. 2;

Fig. 8 is a diagrammatic view showing the power cells used in the present invention and the manner of connecting the same to the electronic circuit;

Fig. 9 is an illustration of the waveform of the resultant pulsing voltage from the bandage;

Fig. 10 is an illustration of the waveform of the resultant pulsing current generated in the patient's body;

Fig. 11 is a perspective view of the underside of the first or lower unit, illustrating the manner of removal of the backing sheet;

Fig. 12 is a diagrammatic view showing the first unit as applied against a patient's body and the second unit about to be applied upon the first unit;

Fig. 13 is a circuit diagram of the circuit used in the bandage;

Fig. 14 is a diagrammatic perspective view showing a modified form of lower unit and a modified form of first printed circuit board;

Fig. 15 is a simplified perspective view of an opto-electronic coupled circuit arrangement;

Fig. 16 is a simplified perspective view of a capacitive coupled circuit arrangement; and

Fig. 17 is a simplified perspective view of a direct coupled circuit arrangement.

Before describing the invention in detail, it may be useful to define certain terms used in the application. The term "bandage" is intended to refer to any type of dressing which might be applied over a wound, injury, incision, sprain or other injury. The term "self-contained" means that the bandage is operative as a single unit and need not be connected to any external power supply in order to be operative. The term "constant voltage" as used herein refers to DC voltage. The term "patient" and "person" are used interchangeably to refer to the individual upon whom the bandage is to be used. When it is stated that the bandage is applied "adjacent to" the injured portion, this should be understood to include both application directly upon the injured portion and application near to, but not directly upon, the injured portion. Finally, in referring to the pain-treating aspects of the present invention, the terms"block" and "mask" are used interchangeably to refer to the manner of treatment. That is, while the mechanism of operation is not entirely understood, it has been discovered and is medically recognized that certain pulsing low electrical currents interfere with the transmission of pain signals by the peripheral nervous system and through the central nervous system to the brain. For convenience, this pain interference by these pulsing electric currents is referred to herein as "pain-blocking or "pain-masking".

Referring now to Fig. 1, the bandage in accordance with the principles of the present invention is illustrated therein in enlarged form and is generally designated 20. It will be understood that the thickness of the bandage 20 is kept to a minimum, consistent with the various components of the invention which must be included therein, but it can be generally stated that the bandage 20 is relatively thin so that it can be applied to, and worn by, a patient without creating any large or unsightly bulge. The bandage 20 includes a lower unit or first unit generally designated 22 which is applied directly to a patient's body and a second unit or upper unit generally designated 24 which is applied to the first unit 22.

The details of these units may be more apparent by reference to Figs. 2-7. The lower unit 22 includes a housing or body member 26 having a lower surface 28 adapted to be applied directly against the patient's skin and an opposed upper surface 30. A series of outer or peripheral openings 32 are provided in the housing 26, extending completely between the lower and upper surfaces 28 and 30. An inner opening 34 is provided centrally in the body member 26, again extending completely between the upper and lower surfaces. As can be seen, the inner opening 34 is completely separated from the outer or peripheral openings 32. Advantageously, the body member 26 is fabricated of foam plastics, silicone, or other suitable material which is both flexible and somewhat compressible.

A first printed circuit board 36 is mounted upon the upper surface 30 of the body member. This printed circuit board, as shown in Figs. 4 and 5, includes a lower or undersurface 38 and a top or upper surface 40. Electrode means are provided on the undersurface 38 of the printed circuit board 36. This electrode means includes an outer electrode 42 aligned to overlie the outer openings 32 and an inner electrode 44 aligned to overlie the inner opening 34. These electrodes are formed of dissimilar metals. Advantageously, the inside electrode 44 is formed of copper while the outside electrode 42 is formed of zinc or chromium plated over copper. On the upper surface 40 of the printed circuit board 36, a coil or spiral 46 is provided. A post or terminal 48 extends through the printed circuit board 36 to connect the outer end of this coil 46 with the outer electrode 42. Another post or terminal 50 extends through the printed circuit board 36 to connect the inner end of the coil 46 with the electrode 44. As shown, the coil or spiral is formed as a squared spiral in order to get the maximum number of turns. However, any suitable type of wound coil or spiral can be used.

The arrangement described thus far forms the lower unit 22. The printed circuit board 36 is attached to the body 26 by a suitable permanent adhesive, preferably extending about the peripheral edges. The only feature of the lower unit not described thus far is the electrolyte 52 which is provided in, and which substantially completely fills, the openings 32 and 34. The electrolyte 52 is in the form of a gel or a foam, either of which has sufficient viscosity to remain in position within the openings. The electrolyte is polymeric to prevent

molecules thereof from being absorbed through the skin. It is also flexible to permit suitable flexing of the bandage. Since the specific electrolyte used is not part of the present invention, the composition need not be described in detail. However, it can be stated in general that mixtures of alcohols and salt solutions with gelling agents such as agar, gelatins, celluloses, gums or other suitable substances provide operative electrolytes. Specific forms of electrolyte compositions useful for application to a person's skin include those shown in U.S. Patents Nos. 4,094,822; 3,989,050; 3,658,726; 3,048,549 and 3,027,333.

Before considering the operation of the lower unit 22, attention should be directed to Fig. 11, which shows the lower unit with a removable backing sheet 54 thereon. This backing sheet is advantageously applied across the lower surface 28 of the unit at the time of manufacture, and it remains so attached until the unit is ready to be applied to the patient's skin. In this manner, the electrolyte 52 is maintained sterile. When the doctor or medical technician decides to apply the unit 22 to the patient's skin, he or she simply grasps the backing sheet 54 and peels the sheet away, as illustrated by the arrow in Fig. 11.

Considering the operation of the lower unit 22, that unit generates a substantially constant voltage when it is placed in a position where the electrolyte 52 contacts the patient's skin. Advantageously, the patient's skin is previously abraded by means of a small brush or

eraser, or similar instrument, which removes the dead skin surface and thereby lowers the skin resistance. Alternatively, the patient's skin is pre-wetted with a conductive solution to lower skin resistance. Because the skin is electrically conductive even though it has a certain electrical resistance, there is an electrical flow from the positive electrode 44, through the electrolyte in the opening 34, through the patient's skin to the electrolyte in the outer openings 32, back up to the negative electrode 42, and through the terminal 48, the coil 46 and the terminal 50 to return to the electrode 44, where it thereupon repeats the cycle. This voltage flow is created by the differing electrochemical activity of the metals forming the electrode 44 and electrode 42 of the unit. Since the zinc forming the electrode 42 is more reactive than the copper which forms the electrode 44, there is an ionic reaction which displaces copper ions, thus creating an oxidation-reduction transfer of electrons which sets up the electrical flow. As the electrochemical action continues, a portion of the electrodes become consumed in the reaction, thereby generating a certain heat of reaction. In addition, there is a tendency for the aqueous portion of the electrolyte 52 to be repelled by the electropositive electrode and attracted by the electronegative electrode. This combination of heat of reaction and aqueous repulsion will eventually cause the electrolyte 52 to dry out at the anode, and, when that occurs, the electrical flow terminates. On units thus far constructed and tested, it has been found that the lower units 22 are operative for approximately 48 hours. While the magnitude of the voltage

will obviously vary depending upon sizes, materials and the like, it has been found that units 22 can be expected to generate a substantially constant 0.8 volt during their period of operation.

Referring now to Figs. 6 and 7, there is illustrated therein the second printed circuit board which is designated 56. The second printed circuit board has a lower surface 58 which is directed toward the upper surface 40 on the first printed circuit board. It also includes an upper surface 60 on the opposite side thereof. On the lower surface 58, there is provided another wound coil 62, again shown as a squared spiral. This coil 62 is similar to the coil 46, but has fewer windings in the preferred embodiment. As will be explained, this enables the coils 46 and 62 to coact as a transformer, and the differential in windings permits the transformer to function as a step-up transformer.

Terminals or posts 64 and 66 are connected to the outer and inner ends of the coil 62, respectively, and extend through the printed circuit board 60 to connect to an electronic circuit 68 which is provided at the upper surface 60 of the printed circuit board. In Fig. 7, this electronic circuit 68 is merely shown in a block diagram form, but the circuit itself will be described hereinafter in detail and is shown in Fig. 13. The upper surface of the printed circuit board 56 also carries at least one power source means 70 which provides direct current voltage to the electronic circuit 68. Finally, as perhaps best illustrated in Fig. 2, the entire upper unit 24 is formed as a housing 72, advantageously of the same material as the

housing 26, and it serves to embed and encapsulate the electronic circuit 68 and the power source means 70. Thus, all components above the upper surface 60 of the second printed circuit board are embedded within the housing 72.

As illustrated in Fig. 7, and in more detail on Fig. 8, two leads from the electronic circuit 68 are provided to connect the electronic circuit with the power source means 70. One lead 74 carries on its end a male member 76 adapted for insertion into the power source means 70 and which serves as the negative terminal or connection. Another lead 78 carries on its end a female connector 80 which serves as the positive connector or terminal and is likewise adapted for attachment to the power source means 70 at its opposite end.

The power source means 70 are designed for interconnection with one another by a plug-in type connection, which thereby connects the power cells in series. Specifically, it will be noted that, on each power source means, there is a housing 82 having a projecting terminal or male member 84 at one end thereof and a socket or female opening 86 at the opposite end thereof, the socket 86 being designed for reception of the male member 84. In this manner, as illustrated in Fig. 8, the power sources can be interconnected together simply by plugging the male end of one into the female socket of the next adjacent one. Power for each power source is provided by means of a pair of small flat watch batteries 88 which are mounted within the housing 82 and electrically connected to both the male member 84 and socket 86. As a result, when only a single power source 70 is used, as illustrated in

Fig. 7, that power source is connected to the electronic circuit 68 by insertion of the negative connector 76 into the socket 86 and by connection of the positive connector 80 to the male projection 84. For bandages of smaller sizes, e.g., less than three inches square, only a single power source means 70 need be provided and the two batteries 88 give a three volt output. On the other hand, for larger size bandages, two or more power source means are interconnected together in the manner illustrated by the arrows in Fig. 8. With two interconnected power sources, the output will be six volts, with three, the output will be nine volts, and so on.

If attention is now directed to Fig. 13, there is illustrated therein the electronic circuit 68 used in conjunction with the bandages. In this circuit, it can be seen that the coils 46 and 62, namely, the confronting coils from the two printed circuit boards, coact to form an inductive electrical coupling means or transformer. When mutual inductance exists between coils in separate circuits, these circuits are considered to be inductively coupled. The effect of the mutual inductance is to transfer energy from one circuit to the other by transformer action. That is, the current flowing in one circuit as a result of a voltage applied to that circuit produces a magnetic flux which induces a voltage in the coupled circuit, thereby resulting in a transfer of energy from the first or primary circuit to the coupled or secondary circuit. When two coils, like coils 46 and 62, are inductively coupled, they constitute the equivalent of a transformer. In practice, as shown in Fig. 2, a very

thin non-conductive film 90, which can even be a sprayed film, is positioned between the two coils to prevent them from shorting against one another.

In Fig. 13, the power means 70 is connected to leads 92 and 94 which connect the power cell to the primary winding or coil 62. An RC circuit including a resistor 96 and capacitor 98 is connected across the lines 92 and 94. This RC circuit serves as a time constant circuit to determine the frequency of oscillation of the voltage output. The RC circuit is connected with an uni-junction transistor 100 which in turn has a load resistor 102 connected between the line 92 and one transistor base. A coupling capacitor 104 is connected by a lead 106 to a pair of transistors 108, 110, connected in a Darlington configuration. A bias resistor 112 connects between the line 106 and the line 92. This resistor 112 provides transistor bias as well as a discharge path for the coupled circuits. The two transistors 108 and 110 serve as a current amplifier and not only provide current to the primary coil 62, but, in addition, serve as a buffer to prevent loading of the uni-junction transistor 100. A free-wheeling diode 114 is connected across the primary winding 62 to prevent inductive kick-back voltages from destroying the Darlington arrangement. On the secondary side of the circuit, a rectifying diode 116 is provided to remove any negative pulses. Operationally, the uni-junction transistor 100 creates a series of voltage spikes as illustrated in Fig. 9. These spikes have a very sharp rise time and a relatively sharp decay time, as shown. Because of the arrangement of the primary and

secondary coils 62 and 46, the resulting transformer is of a step-up type, which provides an increase in the amplitude of the voltage delivered to the secondary 46. If the arrangement is reversed, so that the coil 62 has more windings, the resulting transformer is of a step-down type which produces an increase in current in the secondary coil.

The bandage of the present invention uses a flashing signal light, which operates when the bandage is activated by placing the same in contact with the patient's skin. The actual placement of the tiny signal lamp is now shown, since this can be varied as a matter of aesthetics. However, the circuit diagram of Fig. 13 includes a separate signal light circuit. This separate circuit is needed because the normal operational frequency of voltage spikes from the transistor 100 is relatively rapid, e.g., one hundred pulses per second, and that frequency is too rapid for visual observation of the blinking or flashing effect of the light.

The separate circuit for the light, shown at the top of Fig. 13, includes a pair of steering diodes 118, 120, each of which is connected with a load resistor 122, 124, respectively, to control the charge and discharge of a timing capacitor 126 which, in turn, determines the frequency of flashing of the light. A pair of Schmitt triggers are connected on opposite sides of the timing capacitor 126. These Schmitt triggers are ultra-high speed switching devices. A high resistance isolating resistor 132 is connected between the triggers 128, 130. Another Schmitt trigger 134 is connected along a line 136 which connects the lamp circuit to the lower voltage circuit. A light emitting diode 138, which forms the blinking signal light, is likewise provided in line with the trigger 134.

Fig. 9 illustrates the resultant voltage output from the bandage of the present invention. The lower unit 22, as previously described, generates a substantially constant current which is designated X in Fig. 9. The voltage spikes or pulses from the circuit 68 are superimposed or added upon the constant voltage X from the lower unit, thereby creating a waveform as illustrated in Fig. 9. The magnitude of these spikes is shown as Y. Thus, the waveform shown in Fig. 9 can be considered to be the resultant pulsing voltage being generated by the entire bandage and being transmitted through the electrolyte and to the patient's skin. Because of the inherent resistance of the patient's skin, the resultant pulsing voltage is converted within the patient's body into a pulsing current. The general waveform of this current is illustrated in Fig. 10. As can be seen, the current maintains a constant lower value of A but periodically rises to a higher level B where it remains for a short interval of time before returning to level A. It will be noted that both the rise time and the decay time of the current are very rapid thus creating a pulsing current wave of the form illustrated in Fig. 10.

As examples of the magnitude of values attendant to bandages of the present invention, and without in any way trying to limit the present invention to such values, it can be stated that a typical value of X in Fig. 9 might be 0.8 volt and a typical value of Y in Fig. 9 might be 1.8 volts, which means that 1 volt spikes are being superimposed upon a 0.8 volt constant voltage. The frequency of the spikes is about 100 pulses per second. These figures would hold true for a bandage of relatively

small size, e.g., an 1.5" x 1.5" bandage. On a larger bandage, e.g., 3" x 4" or 4" x 6", the value of Y in Fig. 9 may be 9.8 volts, meaning that 9 volt spikes are being superimposed upon a constant 0.8 volts. In connection with Fig. 10, a typical value of A may be 100 microamps and a typical value of B may be 200 microamps, meaning that, within the patient's body, there is a constant 100 microamp current being delivered with frequent pulses raising that value to 200 microamps. All of the empirical values are by necessity calculated with the ultimate pulsing current values in mind. That is, it is recognized that, above a level of 300 to 400 microamps, there is a discomfort or pain index for most patients. Accordingly, the bandages are designed to keep the values well within patient tolerance levels and, at the present time, it is believed that a range of 10 to 100 microamps is the most effective for the combination of patient comfort and the requisite pain-blocking function.

As previously indicated, the lower units 22 may be expected to have a useful life of approximately 48 hours or two days. On the other hand, the upper units 24 have a considerably longer life span, e.g., ten days. As a result, the doctor or technician who provides the bandage units to the patient may provide one upper unit 24 and five lower units 22 which will then permit ten days of continuous pain-relieving treatment of a patient's injury. All of the components of the bandage 20 are normally interconnected with each other by means of suitable peripheral adhesives, but, if the lower units 22 are to be continually replaced, some other form of attachment means,

for example, an overwrap, may be used. Thus, in reference to Fig. 12, there is illustrated the lower unit 22 applied directly against the patient's skin S. The electrical flow path from that lower unit is demonstrated by the arrows. After the lower unit is prepared for application, for example, by exposing the pressure sensitive adhesive surrounding the peripheral edge of the lower surface 28 by removal of the backing sheet 54, the lower unit is then properly situated on the patient's body covering the injury or injured portion. The upper unit 24 is then activated, placed above, and brought down into contact with, the lower unit. Some means must be provided to keep the upper unit from being activated while it is in storage, or else the power source means 70 would become depleted prior to use. One simple way to accomplish this is by placing a plastics strip adjacent the power cells 88 to keep them from making contact until the strip is pulled out to activate the circuit. As previously indicated, a non-conductive film 90 should be placed between the two units to prevent shorting of the coils against one another. This film 90 can be applied by a simple aerosol spray across the upper surface 38 of the printed circuit board 36. The upper unit 24 is then placed into contact with the lower unit and is retained in place by means of adhesive tape, a flexible overwrap such as an elastic bandage, or any other suitable means.

If attention is directed to Fig. 14, there is shown therein a modified form of lower unit 22'. This includes a body portion 26', which has a pair of triangular openings 32' and 34' of substantially equal size and shape,

diagonally separated from one another. The electrode 52 fills both openings in the body 26'. As a result, when the printed circuit board 36' is applied over the body 26', and maintained in position by suitable adhesive such as that peripherally arranged in Fig. 14 and illustrated as 49, the printed circuit board will be attached to the body portion to form the modified lower unit, and, in such modified lower unit, the positive and negative electrodes will each be aligned over an opening which contains the electrolyte. This type of configuration is advantageously used on the smaller sizes of bandages.

While the bandage thus far described uses inductively coupled circuits, created by the separate but confronting coils 46 and 62, this invention clearly comprehends the use of other types of coupled circuits. Any two electric circuits are considered to be coupled if energy can be transferred electrically or magnetically from one to the other. Since the present invention involves two circuits, one in the lower unit 22 and one in the upper unit 24, the coupling of these circuits permits energy transfer between them for accomplishing the beneficial effects of the present invention. Figs. 15, 16 and 17 illustrate, respectively, opto-electronic, capacitive and direct coupled circuits, all of which can be used in lieu of the inductive coupled circuit heretofore described.

Fig. 15 illustrates the opto-electronic or optical coupling arrangement. In such arrangement, a light emitting device 150, such as a light emitting diode, is provided in the upper unit 24, to provide a light pulse through an opening 152 in the printed circuit board 56. An

aligned opening 154 in the printed circuit board 36 overlies a light-activated device 156 in the lower unit 22. The coupling is accomplished by impingement of light pulses from 150 onto 152.

Fig. 16 illustrates a capacitive coupling arrangement. A first capacitor plate 158 is etched on the printed circuit board 56 and an opposed second capacitor plate 160 is etched onto the upper surface of the printed circuit board 36. These capacitor plates are advantageously coated with an insulating wax film. A connector 162 on the lower unit 22 fits into a receptacle 164 on the upper unit 24 to provide a common line.

Finally, in Fig. 17, a direct circuit coupling arrangement is illustrated. In this arrangement, a series of upstanding connector pins 162 on the lower unit 22 fit into a corresponding series of corresponding receptacle holes 164 on the upper unit 24. This enables direct current electrical energy from the lower unit 22 to travel through the pins 162 into the upper unit, combine with the electrical energy from the upper unit, and thereby permit the combined or coupled electrical energy to be delivered to the patient's skin.

It is within the clear purview of this invention to use differing sizes, shapes and thicknesses of materials, to use different materials, to use different electrode arrangements, printed circuit layouts, a variety of different electrolytes, opening sizes, configurations and the like. In short, various changes and modifications apparent to those skilled in the art may be made without departing from the scope of the invention as defined in the appended claims.

Claims:

1. A flexible, self-contained bandage for application adjacent to an injured portion of a patient's body, to block or mask pain arising from the injury, said bandage being characterised in that it includes:

a first unit adapted to be applied directly to the patient's body;

a second unit applied upon said first unit, said second unit including means for generating a series of voltage pulses; and

means for generating a substantially constant voltage at said first unit,

said first unit and said second unit and said generating means being coupled for superimposing said voltage pulses upon said constant voltage to form a resultant pulsing voltage which is transmitted to the patient's skin to cause low current electrical pulses which block or mask the pain.

2. A bandage as defined in claim 1, wherein said means for generating a substantially constant voltage includes spaced first and second opening means in said first unit having electrolyte therein, which contacts against the patient's skin, and first and second electrodes formed of dissimilar metals contacting respectively against the electrolyte in said first and second opening means, whereby an electrochemical reaction occurs through said electrolyte to generate said constant voltage.

3. A bandage as defined in claim 1, wherein said second unit includes power cell means and an electronic circuit connected therewith to convert the voltage from said power cell means into said series of voltage pulses.

4. A bandage as defined in claim 1 wherein said generating means are coupled by an electrical circuit coupling arrangement.

5. A bandage as defined in claim 4 wherein said circuit coupling arrangement is, alternatively, an inductive coupling.

6. A bandage as defined in claim 4, wherein said circuit coupling arrangement is a direct coupling.

7. A bandage as defined in claim 4, wherein said circuit coupling arrangement is an opto-electronic coupling.

8. A bandage as claimed in claim 4, wherein said circuit coupling arrangement is a capacitibe coupling.

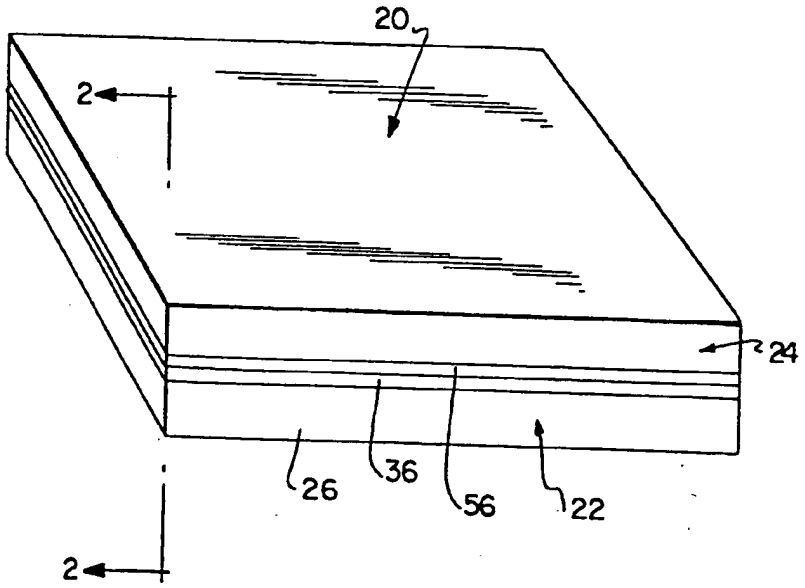
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FIG. 1

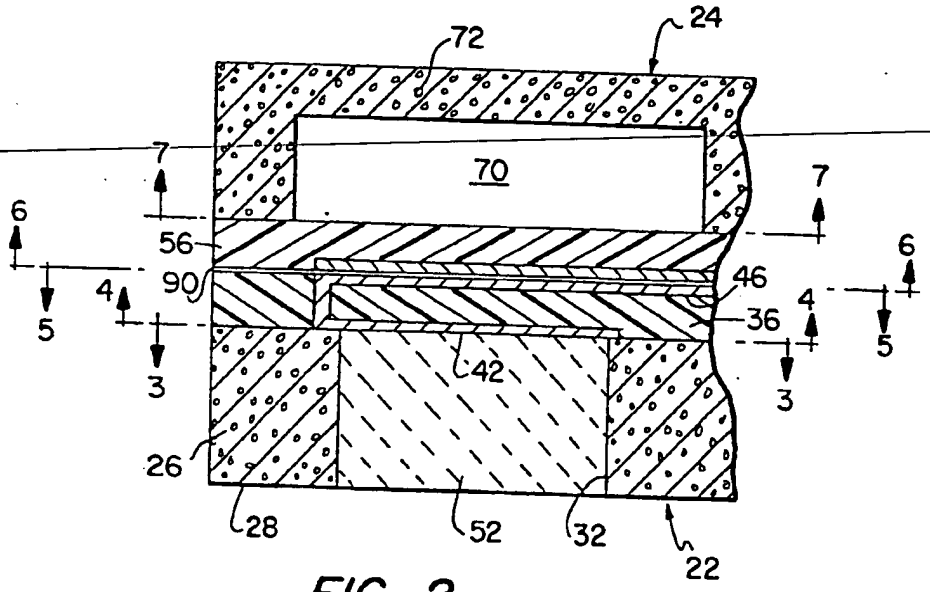
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FIG. 2

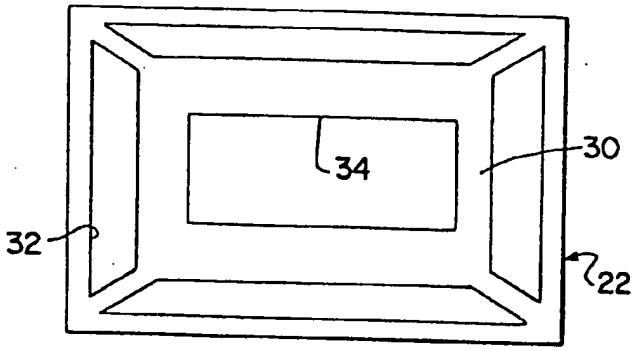


FIG. 3

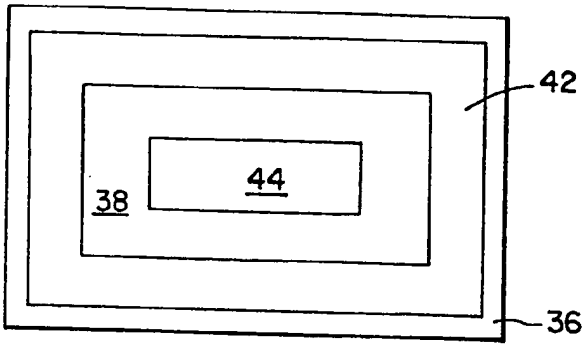


FIG. 4

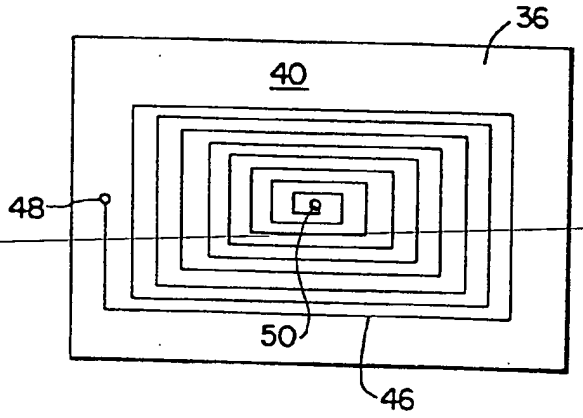


FIG. 5

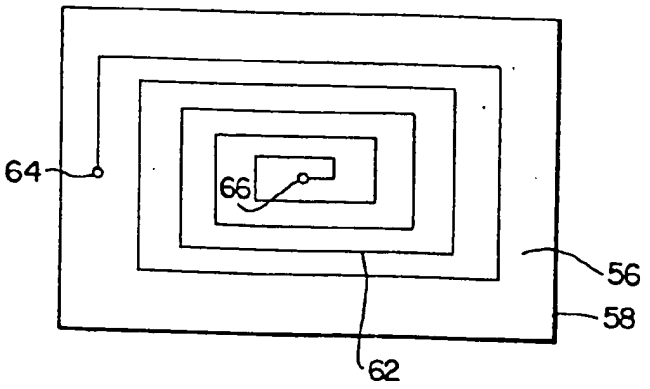


FIG. 6

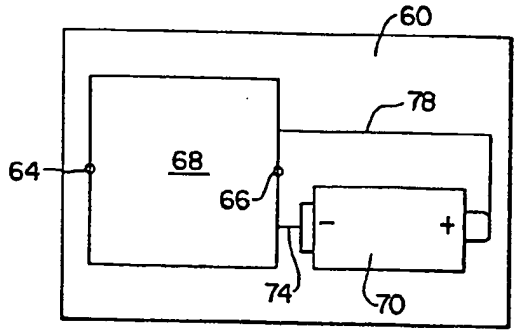


FIG. 7

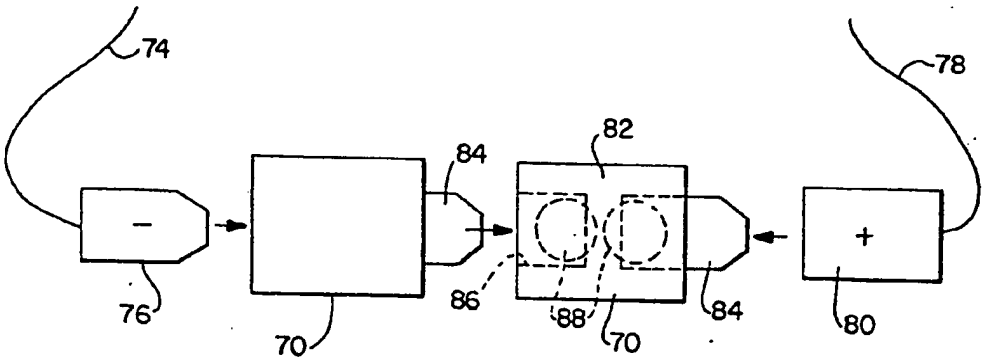


FIG. 8

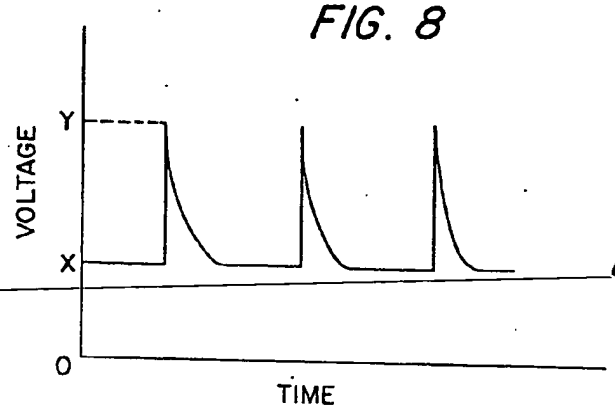


FIG. 9

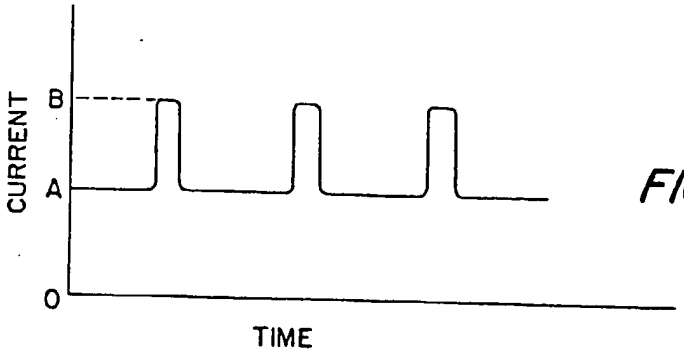


FIG. 10

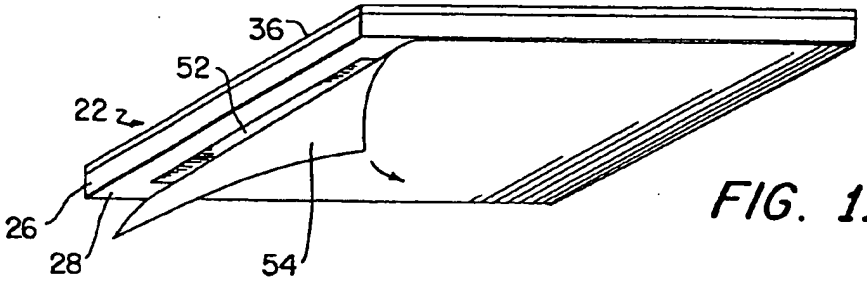


FIG. 11

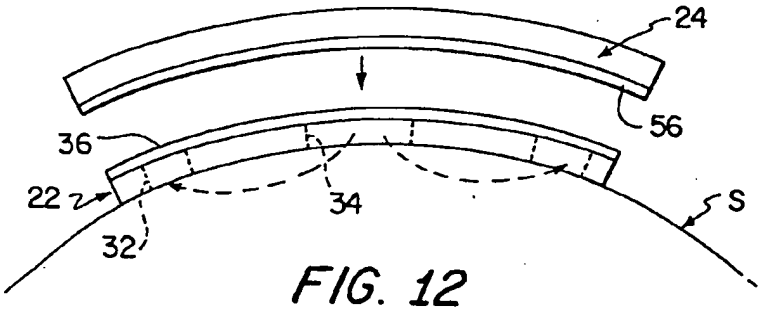


FIG. 12

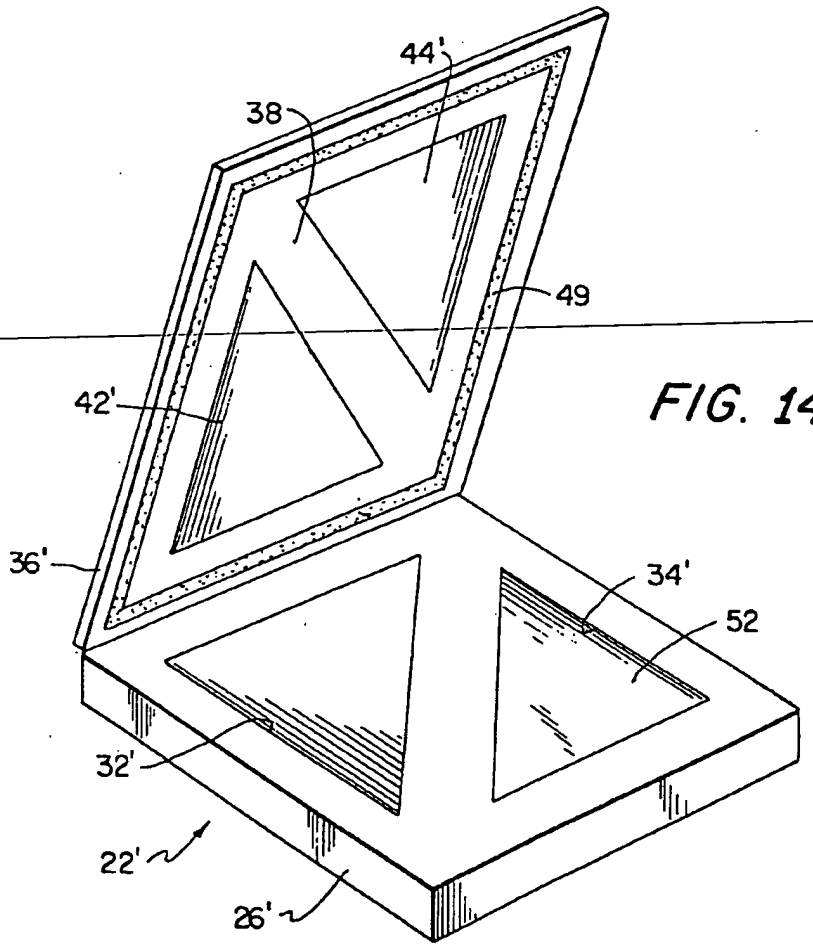


FIG. 14

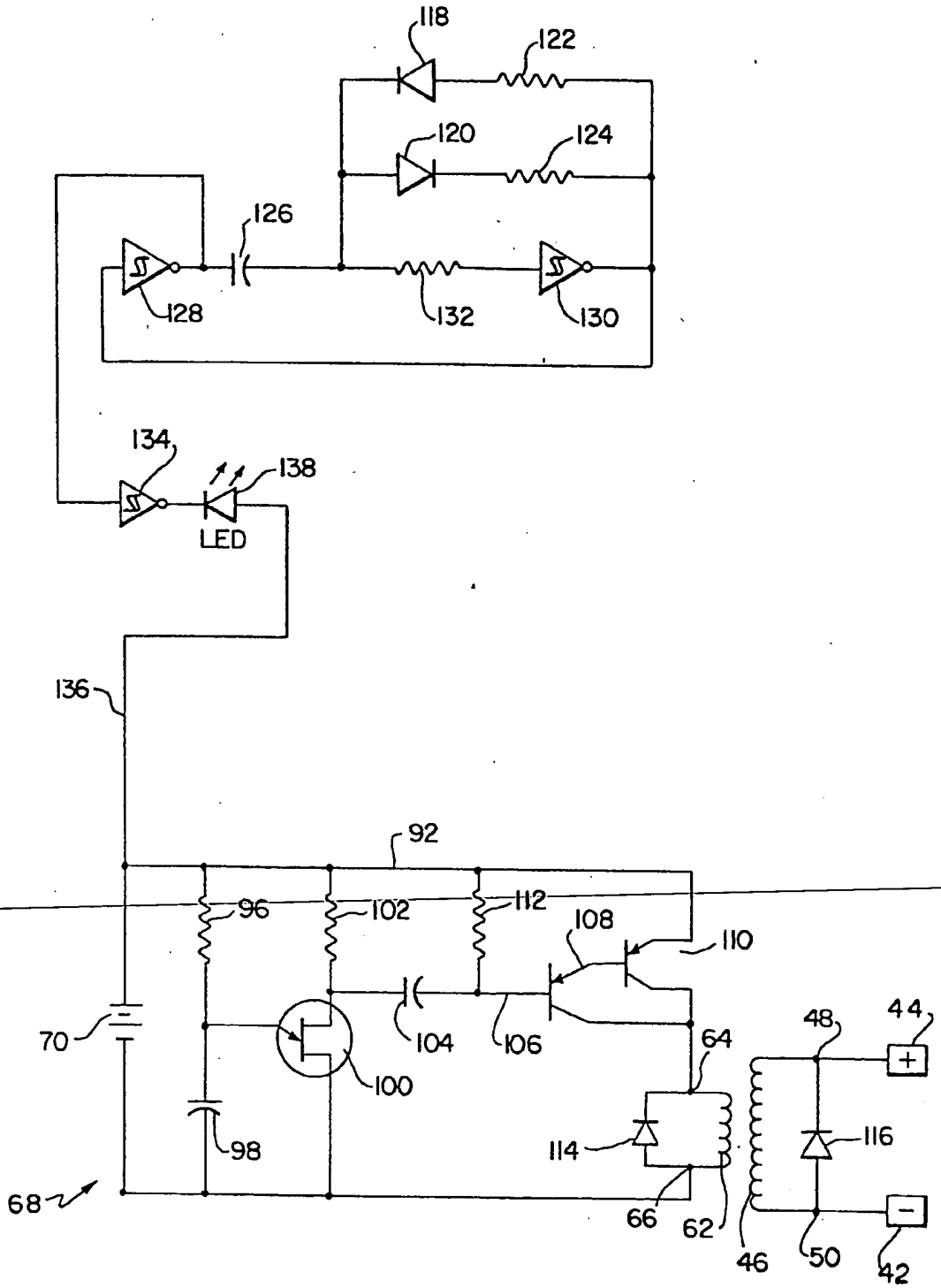
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FIG. 13

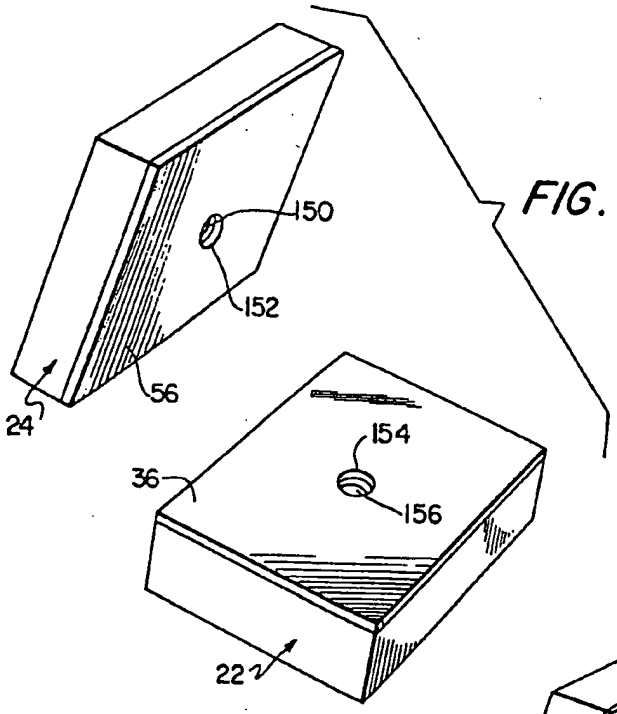


FIG. 15

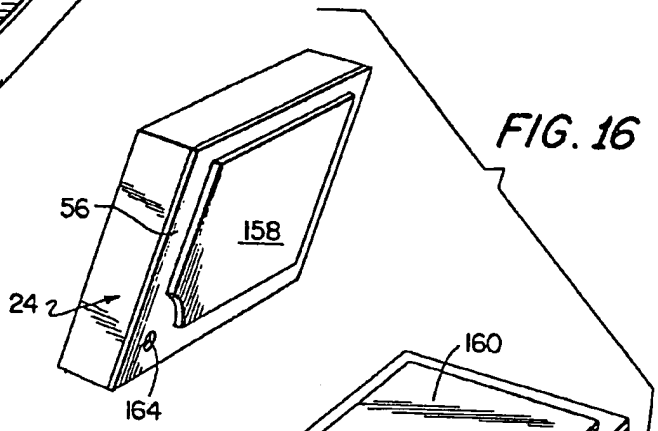


FIG. 16

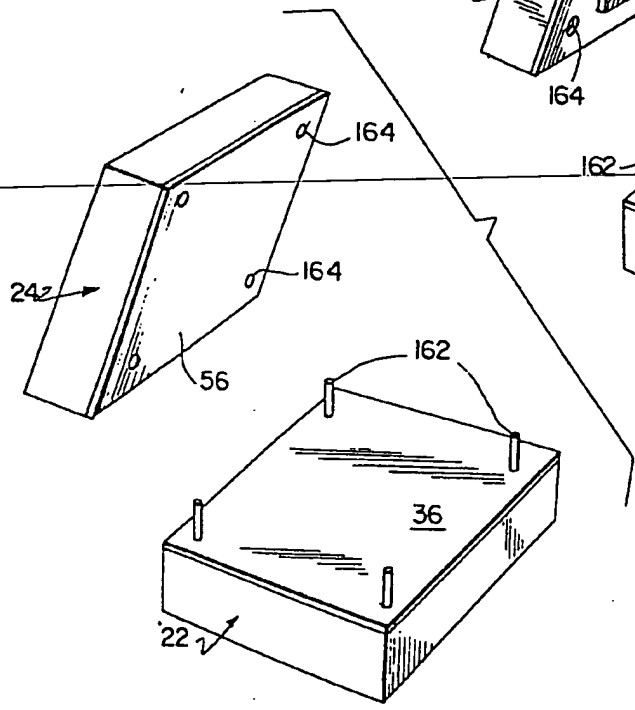


FIG. 17

European Patent Office

# EUROPEAN SEARCH REPORT

Application number
EP 80 30 3577

| DOCUMENTS CONSIDERED TO BE RELEVANT | | | CLASSIFICATION OF THE APPLICATION (Int. Cl.³) |
|---|---|---|---|
| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | |
| | DE - B - 1 065 950 (UNVERFEHRT)<br>* Column 1, lines 37-50 *<br>-- | 1,4,5 | A 61 N 1/34<br>1/24<br>1/04<br>1/18 |
| | FR - A - 2 342 082 (REMPAC)<br>* Page 2, lines 23-39; page 3, line 22 - page 4, line 16; page 5, lines 34,35 *<br>-- | 1,3,4, 6 | |
| | US - A - 3 472 233 (SARBACHER)<br>* Column 2, lines32-73; column 3, lines 34-40; figure 2 *<br>-- | 1 | TECHNICAL FIELDS SEARCHED (Int. Cl.³) |
| | DE - B - 1 006 540 (SUZUKI)<br>* Column 1, line 34 - column 2, line 25 *<br>-- | 2 | A 61 N 1/34<br>1/18<br>1/04<br>1/32<br>1/36<br>1/24 |
| | CH - A - 213 343 (BENOIT)<br>* Page 1, paragraphs 1,2 and 4 *<br>-- | 2 | |
| | GB - A - 407 140 (BLAKOE)<br>* Page 1, lines 62-68 *<br>-- | 2 | CATEGORY OF CITED DOCUMENTS |
| | GB - A - 2 013 502 (BARD)<br>* Page 2, lines 1-59, 120-127 ; figures 1 and 2 *<br>-- | 2,3,6 | X: particularly relevant<br>A: technological background<br>O: non-written disclosure<br>P: intermediate document<br>T: theory or principle underlying the invention<br>E: conflicting application<br>D: document cited in the application<br>L: citation for other reasons |
| | US - A - 3 610 250 (SARBACHER)<br>./. | 4-6 | |

| | | | |
|---|---|---|---|
| X | The present search report has been drawn up for all claims | | &: member of the same patent family, corresponding document |
| Place of search<br>The Hague | Date of completion of the search<br>16-01-1981 | Examiner<br>SIMON | |

EPO Form 1503.1 06.78

European Patent Office

# EUROPEAN SEARCH REPORT

Application number

EP 80 30 3577

| DOCUMENTS CONSIDERED TO BE RELEVANT | | | CLASSIFICATION OF THE APPLICATION (Int. Cl. ³) |
|---|---|---|---|
| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | |
| | * Column 2, lines 55-57; column 3, lines 19-34; column 4, lines 54-62 * | | |
| | -- | | |
| | FR - A - 692 669 (VARGES) | 8 | |
| | * Page 2, line 98 - page 3, line 4 * | | |
| | -- | | |
| EP | FR - A - 2 424 033 (BERNARD) | 1,4,5 | TECHNICAL FIELDS SEARCHED (Int. Cl. ³) |
| | * Page 1, lines 14-19; page 3, lines 16-31 * | | |
| | ---- | | |

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